

# Translation

PATENT COOPERATION TREATY

PCT/AT2003/000306



## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12075	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/AT2003/000306	International filing date (day/month/year) 09 October 2003 (09.10.2003)	Priority date (day/month/year) 10 October 2002 (10.10.2002)
International Patent Classification (IPC) or national classification and IPC A61K 9/00		
Applicant GEBRO PHARMA GMBH		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a. ☒ (sent to the applicant and to the International Bureau) a total of 5 sheets, as follows:
    - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
  - ☒ Box No. I Basis of the report
  - ☐ Box No. II Priority
  - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - ☐ Box No. IV Lack of unity of invention
  - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - ☐ Box No. VI Certain documents cited
  - ☐ Box No. VII Certain defects in the international application
  - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 17 March 2004 (17.03.2004)	Date of completion of this report 28 January 2005 (28.01.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AT2003/000306

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☒ the description:
- pages \_\_\_\_\_ 1-9 \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the claims:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ 1-16 \_\_\_\_\_ received by this Authority on \_\_\_\_\_ 29 May 2004 (29.05.2004)
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-8	YES
	Claims	9-16	NO
Inventive step (IS)	Claims	1-8	YES
	Claims	9-16	NO
Industrial applicability (IA)	Claims	1-16	YES
	Claims		NO

**2. Citations and explanations**

Reference is made to the following document:

D1: WO 01/60394

**1. Novelty**

The subject matter of claims 9 to 16 is not novel within the meaning of PCT Article 33(2).

D1 discloses the use of a buffer based on maleic acid for producing a nasally applicable preparation with desmopressin as active substance (see claim 1). The nasal preparation and the method of producing it are likewise described (see example 2).

**2. Inventive step**

The subject matter of claims 9 to 16 does not involve an inventive step within the meaning of PCT Article 33(3).

The problem addressed by the application is the production of a nasal preparation which is better tolerated by the cilia.

The proposed solution involves the use of a buffer based on maleic acid.

The closest prior art is represented by D1, which mentions that the use of maleic acid enables the nasal preparation to be kept free of preservatives, without impairing the stabilizing of the active substance (see page 2, lines 9 to 13). It is generally known that preservatives such as benzalkonium chloride cause damage to the cilia apparatus. Thus a person skilled in the art would be prompted to produce a preservative-free nasal preparation buffered with maleic acid in order to solve the problem of interest.

However, the preparation according to claim 1 expressly contains the preservative benzalkonium chloride, possibly combined with other preservatives, and thus runs counter to expectations.

Therefore the subject matter of claims 1 to 8 involves an inventive step.

### 3. Industrial applicability

The subject matter of claims 1 to 16 has industrial applicability within the meaning of PCT Article 33(4).